No. 17-1880(L)

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

RICHARD STOGSDILL; NANCY STOGSDILL, Parent of Richard Stogsdill, on behalf of themselves and other similarly situated persons; ROBERT LEVIN; MARY SELF, Parent of Robert Levin on behalf of themselves and other similarly situated persons

Plaintiffs-Appellants,

v.

ALEX M. AZAR II, Secretary of Health and Human Services; ANTHONY KECK; SOUTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES; CMS; JOHN DOES 1-20; TIMOTHY HILL, Acting Director for the Center for Medicaid and CHIP Services

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA

FINAL RESPONSE BRIEF FOR FEDERAL APPELLEES

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STATEMENT OF JURISDICTION

Plaintiffs' amended complaint invoked the district court's jurisdiction under 28 U.S.C. 1331 and 28 U.S.C. 1343(3), (4). R.16 at ¶27; JA 162.[1] In 2013, the district court dismissed the claims against the federal defendants. R.42, JA 274. In a series of subsequent orders, the district court resolved the remaining claims against the state defendants, and, on July 25, 2017, issued a judgment and order that completed resolution of all of plaintiffs' claims against all defendants. R.345, JA 7184. Plaintiffs filed a timely notice of appeal on July 27, 2017. R.346. The state defendants filed a timely notice of cross-appeal on August 7, 2017. R.352. This Court has appellate jurisdiction under 28 U.S.C. 1291.

STATEMENT OF THE ISSUES PRESENTED

Plaintiffs are two Medicaid recipients (and their mothers) who receive certain services that, at a State's option, may be provided through waiver programs for home and community-based services. In 2010, South Carolina, with the approval of the Secretary of Health & Human Services (HHS), made changes to the State's waiver programs that reduced or eliminated certain services provided. In this lawsuit, plaintiffs alleged that as a result of those changes, South Carolina was out of

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[1] We cite to the amended complaint, which was the operative complaint at the time the district court dismissed plaintiffs' claims against the federal defendants. Citations to the record include the page or paragraph number therein, in the following form: "R.[docket number] at --." When a document is designated for the Joint Appendix, an additional cite will appear as follows: "JA-."

compliance with its obligations under the Americans with Disabilities Act (ADA), section 504 of the Rehabilitation Act, and the Medicaid statute. Plaintiffs named as defendants both state officials and officials of the U.S. Department of Health & Human Services (HHS). This brief is filed on behalf of the federal defendants, and therefore addresses solely the following questions presented:

1. Whether plaintiffs' claims against the federal defendants fail because the challenged actions are committed to agency discretion by law.

2. Whether the challenge to the approval of 2010 amendments to the State's waiver programs is also moot because those amendments have since expired.

STATEMENT OF THE CASE

I. Statutory and Regulatory Background

A. The ADA and Section 504 of the Rehabilitation Act

The Supreme Court has held that under Title II of the Americans with Disabilities Act, the "unjustified institutional isolation of persons with disabilities is a form of discrimination." *Olmstead v. L.C.*, 527 U.S. 581, 600 (1999). The Supreme Court ruled that States therefore have an obligation to provide community-based treatment for individuals with disabilities where appropriate; where the individuals do not oppose such services; and where "the placement can be reasonably accommodated," taking into account state resources and the needs of other individuals

with disabilities. *Id.* at 607. Section 504 of the Rehabilitation Act, which applies to programs and activities that receive federal financial assistance, likewise prohibits discrimination on the basis of disability. 29 U.S.C. 794(a). This Court has held that the requirements under the ADA and Section 504 regarding community-based treatment are co-extensive. *See Pashby v. Delia*, 709 F.3d 307, 321 (4th Cir. 2013).

As discussed below, the Medicaid program affords States "an opportunity to obtain partial Federal funding to assist in compliance" with the ADA and section 504. Medicaid Program; Home and Community-Based Services (HCBS) Waivers, 76 Fed. Reg. 21,311, 21,312 (Apr. 15, 2011). For example, under the section 1915(c) waiver program described below, a State may provide home and community-based services to waiver recipients in furtherance of its *Olmstead* obligations and then receive (partial) reimbursement from HHS. *Id.* However, "[a] State's obligations under the ADA and section 504 of the Rehabilitation Act" are neither "defined by" nor "limited to[] the scope or requirements of the Medicaid program." *Id.*; Medicaid Program; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Home and Community-Based Setting Requirements for Community First Choice and Home and Community-Based Services (HCBS) Waivers, 79 Fed. Reg. 2948, 2951 (Jan. 16, 2014) (final rule) (same).

B. Home and Community-Based Services (HCBS) Waivers Under Section 1915(c) of the Medicaid Statute

The Medicaid program, established by Title XIX of the Social Security Act, 42 U.S.C. 1396 *et seq*., is a cooperative program between the federal government and the States to provide medical assistance to families with dependent children, and aged, blind or disabled persons, and certain other individuals "whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. 1396-1. The Medicaid program is administered at the federal level by the Centers for Medicare & Medicaid Services (CMS). It provides federal financial assistance to States for the purpose of reimbursing medical care provided to needy individuals. *Wilder v. Virginia Hosp. Ass'n,* 496 U.S. 498, 502 (1990). State participation in Medicaid is voluntary, but those States that elect to participate must comply with requirements imposed by the Medicaid statute and implementing regulations promulgated by HHS. *Armstrong v. Exceptional Child Center, Inc.*, 135 S. Ct. 1378, 1382 (2015); *Wilder*, 496 U.S. at 502.

To receive federal funding, a participating State must develop a "plan for medical assistance" and submit it to the Secretary for approval. 42 U.S.C. 1396a; *Wilder*, 496 U.S. at 502. Upon approval of its state plan, a State becomes entitled to reimbursement by the federal government for a portion of its payments to hospitals and other providers of medical assistance to Medicaid recipients. 42 U.S.C. 1396b(a). This federal contribution to a State's Medicaid expenses is termed "federal financial

participation" (FFP). *See* 42 U.S.C. 1396a; 42 C.F.R. 435.1000. In return for FFP, "the State pays its portion of the costs and complies with certain statutory requirements for making eligibility determinations, collecting and maintaining information, and administering the program." *Arkansas Dep't of Health & Human Servs. v. Ahlborn*, 547 U.S. 268, 275 (2006) (citing 42 U.S.C. 1396a).

The Medicaid statute allows States to provide, with the Secretary's approval, home and community-based services that help a beneficiary receive care at home or in a community setting rather than in a nursing home or other long-term care institution. In 1981, Congress concluded that many individuals residing in Medicaid-funded nursing homes or intermediate care facilities would be capable of living at home or in the community if additional support services were available. *See Sanchez v. Johnson*, 416 F.3d 1051, 1054 (9th Cir. 2005). Congress enacted provisions that allow States to provide case management services, homemaker services, home health aide services, personal care services, and other support services (except room and board) that would enable a beneficiary to remain at home or in a community residential setting rather than entering an institution. Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, § 2176, 95 Stat. 357, 813, (adding 42 U.S.C. 1396n(c)(4)(B)); *see* 42 C.F.R. 440.180 (defining home and community-based services).

States participating in Medicaid are *not* obligated to provide home and community-based services. 42 U.S.C. 1396a(a)(10)(A); *id.* 1396d(a)(1), (5), (17), (21), (28) (listing services that must be provided in State Medicaid plan). They may, however, at their option provide these services to a limited number of beneficiaries under a state "waiver" program authorized by section 1915(c) of the Medicaid statute, codified at 42 U.S.C. 1396n(c). Medicaid generally requires that services offered under the state Medicaid plan be available state-wide, *see* 42 U.S.C. 1396a(a)(1), and that all beneficiaries have access to services of a comparable amount, duration, and scope, *see* 42 U.S.C. 1396a(a)(10)(B). The Secretary, however, may waive these two statutory requirements with respect to the provision of home and community-based services. That waiver permits a state Medicaid program to limit the number of beneficiaries eligible for these services and to treat state payment for services provided under the waiver as reimbursable "medical assistance" authorized under the state Medicaid plan. 42 U.S.C. 1396n(c)(1), (3).

As relevant here, home and community-based services under a waiver are available to individuals in state-specified groups of Medicaid recipients who otherwise would require services at an institutional level. 42 U.S.C. 1396n(c)(1). The Medicaid statute imposes certain conditions on these waiver services. A State must provide assurances that (1) "necessary safeguards * * * have been taken to protect the health

and welfare of individuals provided services under the waiver and to assure financial accountability for funds expended with respect to such services"; (2) it will provide evaluations of individuals' need for certain institutional services and information regarding "feasible alternatives" to services at institutions "if available under the waiver"; (3) the waiver program will be expenditure-neutral with respect to individuals who would need care at an institutional level; that is, the State must reasonably estimate that its average annual per capita expenditures for such individuals with the waiver program will not exceed per capita expenditures without the waiver program; and (4) it will provide information annually regarding the impact of the waiver on "the type and amount of medical assistance provided under the State plan and on the health and welfare of recipients." 42 U.S.C. 1396n(c)(2)(A)-(E).

In addition, the State must make a determination that an individual seeking services under the waiver program meets Medicaid's income, resource, and other eligibility requirements, and that but for the provision of home and community based services, he or she would require the level of care provided in a hospital, nursing facility, or intermediate care facility for the intellectually disabled. 42 U.S.C. 1396n(c)(1). Finally, services under the waiver must be provided "pursuant to a written plan of care." *Id.*

The assurances submitted by the State must be "satisfactory to the Secretary," 42 U.S.C. 1396n(c)(2), and the state Medicaid agency must provide CMS with documentation containing "sufficient information to support" the required assurances. 42 C.F.R. 441.303. A waiver request, or request to amend a previously-approved waiver, "shall be deemed granted unless the Secretary, within 90 days after the date of its submission to the Secretary, either denies such request in writing" or sends a written request for additional information. 42 U.S.C. 1396n(f)(2). The State's request likewise "shall be deemed granted" after the date of receipt of such additional information, unless the Secretary "within 90 days of such date, denies such request." *Id.* Section 1915(c) waivers are effective for an initial term of three years and, at a State's request, "shall be extended for additional five-year periods unless the Secretary determines that for the previous waiver period the assurances provided * * * have not been met." 42 U.S.C. 1396n(c)(3).

States are not required to seek any section 1915(c) waivers and may "choose[] to terminate" an approved waiver before the initial 3-year period or subsequent renewal period expires. *See* 42 C.F.R. 441.307. A State "must notify CMS in writing 30 days before terminating services to beneficiaries." *Id.* CMS may terminate a waiver if, after notice and an opportunity for a hearing, it finds that the State "is not meeting one or more of the requirements for a waiver." 42 C.F.R. 441.304(d).

II. Factual Background

Two of South Carolina's section 1915(c) waiver programs are at issue here. South Carolina's "Intellectually Disabled and Related Disabilities" ("ID and Related Disabilities" or "ID/RD") waiver program serves Medicaid-eligible people who have been diagnosed with an intellectual or related disability. *See* R.118-9, JA 2350; *infra* n.2. Qualifying individuals may receive a range of health care and personal care services in their home or other community setting. Plaintiff Richard Stogsdill receives services under the ID/RD waiver program. *See* R.16 at ¶96, JA 177.

South Carolina's Head and Spinal Cord Injury (HASCI) waiver program provides similar services for Medicaid-eligible individuals who have been diagnosed with such injuries and need a level of care that, absent home or community-based support, would warrant admission to an institution. *See* R.118-9, JA 2349; *infra* n.2. Plaintiff Robert Levin receives services under the HASCI waiver program. *See* R.131 at 4, JA 2543.

In 2010, South Carolina – with the Secretary's approval – adopted amendments to these waiver programs that reduced the amount and scope of certain services available to participating beneficiaries. R.131 at 2, JA 2541; *see* R.118-6, JA 2252. These are the reductions and exclusions that plaintiffs challenged in this lawsuit. R.42 at 4 & n.3, JA 277; R.131 at 2, JA 2541. After the district court dismissed plaintiffs'

claims against the federal defendants, the HASCI and ID and Related Disabilities waiver renewals expired, and CMS approved South Carolina's applications to renew its HASCI waiver (effective July 2013) and its ID and Related Disabilities waiver (effective January 2017) for additional five-year terms.[2]

III. District Court Proceedings

In the amended complaint filed in June 2012, plaintiffs alleged that South Carolina was not in compliance with its obligations under the ADA and Section 504 of the Rehabilitation Act, as a result of South Carolina's reduction in the services provided under its waiver programs. Plaintiffs also alleged state violations of the Medicaid statute and the state Administrative Procedure Act. *See generally* R.16 at pp. 40-41, 45-59, JA 196-197, 201-215.

With respect to the federal defendants, plaintiffs alleged that HHS was failing to perform management and oversight duties with respect to South Carolina's Medicaid program. R.16 at ¶222, JA 198; *see generally id.* at pp. 42-44, JA 198-200. Plaintiffs alleged that by approving reductions in home and community-based waiver services, the federal defendants "disregarded rules requiring services to be provided in the most appropriate and least restrictive setting." *Id.* at ¶60, JA 168. In addition,

[2] *See* https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/?entry=8377; https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/?entry=8379.

plaintiffs alleged that the federal defendants had "fail[ed] to take action to correct actions taken by the State Defendants which improperly limit Plaintiff's access to Medicaid waiver services[.]" *Id.* at ¶154, JA 187.

The federal defendants moved to dismiss the amended complaint for lack of subject matter jurisdiction, or, in the alternative, for failure to state a claim. R.18. They explained that the challenged actions (and inaction) are not subject to review under the Administrative Procedure Act (APA) because they are committed to agency discretion by law. The federal defendants argued in the alternative that plaintiffs lack standing to bring their APA claims because the relief sought would not redress their alleged injuries. *See id.*

At an early stage in the proceedings, the district court granted the federal defendants' motion and dismissed the federal defendants from the case. R.42. JA 274. The district court agreed that the challenged actions were committed to the Secretary's discretion by law. *Id.* at 12-13, JA 285-286. The court reasoned that nothing in the Medicaid statute indicates that a private party can force the federal government to undertake a compliance action or seek judicial review of an agency's determination not to undertake such enforcement action. *Id.* The court further explained that plaintiffs failed "to identify a specific final agency action that has caused their alleged injuries and instead make only broad, general allegations about the

CMS and the Federal Defendants and their duties in administering the Medicaid Act." *Id.* at 13, JA 286. In light of these rulings, the court found it unnecessary to reach the federal defendants' alternative argument that plaintiffs lacked standing. *Id.* at 15, JA 288.

In separate subsequent orders, the district court resolved the remaining claims against the state defendants on independent legal grounds. R.131, JA 2540; R.193, JA 2963; R.249, JA 4535; R.344, JA 7144; R.345, JA 7184.

SUMMARY OF ARGUMENT

Under the APA, Congress's authorization of judicial review does not extend to challenges to "agency action [that] is committed to agency discretion by law." 5 U.S.C. 701(a)(2). Here, plaintiffs seek review of the nature and extent of HHS's monitoring and enforcement of South Carolina's compliance with the Medicaid statute. Decisions of this sort are quintessential matters of agency discretion. Plaintiffs also object to HHS's approval of 2010 amendments to South Carolina's HCBS waiver programs. However, under the plain terms of the Medicaid statute, such a waiver program may be approved as long as the assurances submitted by the State are "satisfactory to the Secretary." 42 U.S.C. 1396n(c). Thus, the approval decision is committed to agency discretion by law.

In arguing to the contrary, plaintiffs fundamentally misunderstand the relationship between HHS's approval of a state HCBS waiver program under the Medicaid statute and a State's obligations to comply with the ADA and Rehabilitation Act. HHS's approval of a state HCBS program in no way relieves a State of the obligations that are independently imposed under these other statutes.

Plaintiffs' challenge to HHS's approval of the 2010 amendments to the State's waiver programs is also moot. Those approvals pertained to waiver programs that have expired. See R.118-9, JA 2349-2350; *supra* n.2. HHS has since approved additional renewals for both waiver programs, in new decisions supported by new administrative records. See *supra* n.2. Plaintiffs have not challenged the approvals of the renewed waiver programs. And, in any event, setting aside such approvals would not redress their alleged injuries. State participation in HCBS waiver programs is voluntary, and a State has the option to terminate participation before expiration of its program's current term. Thus, plaintiffs' alleged injuries would not be redressed by relief against the federal defendants.

STANDARD OF REVIEW

The district court's dismissal of the complaint is subject to de novo review in this Court. *Angelex Ltd. v. United States*, 723 F.3d 500, 505 (4th Cir. 2013).

ARGUMENT

I. The Challenged HHS Actions are Committed to Agency Discretion by Law.

Under the ADA, South Carolina has an obligation to provide community-based treatment for individuals with disabilities where appropriate, if the individuals do not oppose such services and the placement can be reasonably accommodated, taking into account state resources and the needs of other individuals with disabilities. *Olmstead v. L.C.*, 527 U.S. 581, 607 (1999). The State has an analogous obligation under section 504 of the Rehabilitation Act. *Pashby v. Delia*, 709 F.3d 307, 321 (4th Cir. 2013).

The Medicaid program affords States "an opportunity to obtain partial Federal funding to assist in compliance" with the ADA and section 504. 76 Fed. Reg. at 21,312. Under the section 1915(c) waiver program, a State may provide home and community-based services to waiver recipients in furtherance of its *Olmstead* obligations and then receive (partial) reimbursement from HHS. *Id.* However, "[a] state's obligations under the ADA and section 504 of the Rehabilitation Act are not defined by, or limited to, the services provided under the State's Medicaid program." 79 Fed. Reg. at 2951.

The plaintiff Medicaid recipients contend that as a result of changes that South Carolina made to its waiver programs in 2010, the State is not in compliance with its obligations under the ADA and section 504 of the Rehabilitation Act. The federal government takes no position on the merits of those claims. This Court should

affirm the dismissal of the claims against the federal defendants, however, because the challenged HHS actions and inaction are committed to agency discretion by law.

Although the APA contains "comprehensive provisions for judicial review of 'agency actions,'" a plaintiff "must first clear the hurdle of § 701(a)." *Heckler v. Chaney*, 470 U.S. 821, 828 (1985). Under section 701(a), there is no APA review of "agency action [that] is committed to agency discretion by law." 5 U.S.C. 701(a)(2). It is well-settled that "an agency's decision not to * * * enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion." *Chaney*, 470 U.S. at 831. Accordingly, "the presumption of reviewability normally accorded agency action does not apply to agency decisions not to undertake enforcement actions." *Sierra Club v. Larson*, 882 F.2d 128, 131 (4th Cir. 1989).

A federal agency's day-to-day monitoring of compliance with statutory requirements is similarly unreviewable under the APA. *Clear Sky Car Wash LLC v. City of Chesapeake*, 743 F.3d 438, 445 (4th Cir. 2014). Indeed, "monitoring is a form of enforcement," and "enforcement decisions involve a complicated balancing of a number of factors which are peculiarly within the agency's expertise, and the agency is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities." *Madison-Hughes v. Shalala*, 80 F.3d 1121, 1126 (6th Cir. 1996).

The district court properly applied these principles to conclude that the challenged HHS actions are committed to its discretion by law. Plaintiffs alleged that HHS failed to monitor and enforce state compliance with Medicaid statute requirements with respect to South Carolina's optional HCBS waiver programs. *See, e.g.*, R.16 at ¶¶ 154, 222, 226, 236, JA 187, 198, 200. For example, the amended complaint alleged that the federal defendants failed "to perform the duties intended by Congress in the management and oversight of the Medicaid waiver programs in South Carolina." R.16 ¶222, JA 198. Such oversight and management decisions are quintessential matters that are committed to agency discretion by law.

Plaintiffs also objected to HHS's approval of 2010 amendments to South Carolina's waiver programs. *See, e.g.*, R.16 at ¶¶ 223, 232-233, JA 198-200. But under the plain terms of the Medicaid statute, HHS may approve a state waiver program as long as the assurances submitted by the State are "satisfactory to the Secretary." 42 U.S.C. 1396n(c)(2). Moreover, Congress provided that the State's waiver amendment application "shall be deemed granted" unless the Secretary either denies the application or requests additional information. 42 U.S.C. 1396n(f)(2). The Medicaid statute thus commits to the agency's discretion the decision whether to approve the terms of these optional waiver programs.

At bottom, plaintiffs' position reflects a basic misunderstanding of the relationship between HHS's approval of a state waiver program, on the one hand, and the requirements of the ADA and section 504 of the Rehabilitation Act, on the other. *See* R.28 at 3-4. As the federal defendants emphasized below, HHS's approval of a state waiver program in no way relieves the State of the obligations independently imposed under the ADA and section 504 of the Rehabilitation Act. In administering the Medicaid statute, the Secretary does not enforce ADA or Rehabilitation Act requirements, and the Medicaid program neither defines nor limits states' obligations to provide home and community-based services under other federal statutes and the Supreme Court's decision in *Olmstead*. 79 Fed. Reg. at 2951, 2963.

That does not mean that the Secretary cannot, as a matter of policy, encourage states to participate in the optional waiver program so as to provide opportunities for individuals to obtain home and community-based services. *See Olmstead*, 527 U.S. at 601 (noting that U.S. Amicus Brief states that HHS "'has a policy of encouraging States to take advantage of the waiver program'"); 79 Fed. Reg. at 2956. But Congress made clear that States have the *option* to provide Medicaid coverage for such services and are not required to do so by the Medicaid statute. *See* 42 U.S.C. 1396a(a)(10)(A); *id.* 1396d(a)(1), (5), (17), (21), (28) (home and community-based services not included on list of services that must be provided as part of the State Medicaid plan); 42 U.S.C.

1396n(c) (home and community-based services can be covered under optional waiver program). Accordingly, the extent to which the Secretary considers factors such as compliance with *Olmstead* requirements in approving a section 1915(c) waiver thus is committed to agency discretion.

The cases on which plaintiffs rely in their opening brief provide no support for their claims against the federal defendants. Plaintiffs rely (Br. 32) on *Bowen v. American Hospital Association*, 476 U.S. 610 (1986), but that case invalidated certain regulations on the ground that they were not authorized by Section 504 of the Rehabilitation Act. *Id.* at 643. This case is not a challenge to final regulations issued pursuant to section 504, and *Bowen* is therefore inapposite.

Plaintiffs also cite (Br. 33, 35) the South Carolina court of appeals decision that concluded that the state defendants' application of the 2010 caps on services to plaintiff Stogsdill's case "violates the Americans with Disabilities Act (ADA) as set forth in *Olmstead*[.]" *Stogsdill v. South Carolina Dep't of Health & Human Servs.*, 763 S.E.2d 638, 643 (S.C. Ct. App. 2014), *cert. dismissed as improvidently granted*, 781 S.E.2d 719 (S.C.) (per curiam), *cert. denied*, 137 S. Ct. 278 (2016). But that ruling only underscores the point that relief under the ADA is properly sought against the State, not against the federal defendants. The *Stogsdill* decision further demonstrates that the

Secretary's approval of a waiver program amendment is *not* the legal equivalent of a determination that a state has complied with *Olmstead* obligations under the ADA.

Likewise, in *Pashby*, this Court ruled in favor of plaintiffs by affirming the district court's entry of preliminary injunctive relief on ADA and Rehabilitation Act claims for violation of *Olmstead* requirements in an action brought against state officials. 709 F.3d at 321-24. The Court based its ruling on application of Department of Justice regulations implementing Title II of the ADA to the state defendants' actions; it did not review HHS action (or inaction) in administering the Medicaid statute. See *id.* at 322. Indeed, HHS does "not administer or enforce the ADA." 79 Fed. Reg. at 2963. There is no authority for plaintiffs' claims against HHS to proceed.

II. Plaintiffs' Challenge to the Approval of the 2010 Amendments to South Carolina's Waiver Programs is also Moot and Plaintiffs' Alleged Injuries are not Redressable by Relief Against the Federal Defendants.

In addition to the fatal defects discussed above, plaintiffs' challenge to HHS's approval of 2010 amendments to the State's waiver programs is also moot. Those amendments pertained to waiver programs that have since expired. *See* R.118-9, JA 2349-2350; *supra* n.2. Any relief ordered by the Court would be wholly ineffective because the challenged approvals by the Secretary – and the administrative records that support those decisions – are no longer effective. *Murphy* v. *Hunt*, 455 U.S. 478,

481 (1982) (case is moot "when the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome") (quotations omitted).

The Secretary subsequently approved separate 5-year renewals for the ID and Related Disabilities waiver (effective January 2017) and the HASCI waiver (effective July 2013). *See supra* n. 2. Plaintiffs have not challenged the subsequent approvals of the ID/RD and HASCI waiver programs, and for good reason. Even if a court had authority to set aside HHS's approvals of those programs (which it does not), such relief would not redress plaintiffs' asserted injuries because a State has no obligation to participate in an HCBS waiver program in the first place. As explained above, a State may choose to provide coverage under an optional HCBS waiver program, but it is not required to do so under the Medicaid statute. *See* 42 U.S.C. 1396a(a)(10)(A); 42 U.S.C. 1396n(c). And even once a State has chosen to participate in a waiver program and has obtained approval from the Secretary, it may "choose[] to terminate" the waiver before the program's term expires. 42 C.F.R. 441.307(a). Thus, if a court were to invalidate HHS's approval of a State's waiver program, the State could, consistent with the Medicaid statute, cease providing the HCBS services entirely.

For these reasons, plaintiffs also lack standing with respect to their claims against the federal defendants. To have standing under Article III, plaintiffs must allege an "injury in fact" that is "fairly traceable" to defendants' challenged actions,

and that is likely to be redressed by the relief requested. *Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992) (quotations omitted). Plaintiffs "bear[] the burden of establishing injury, traceability, and redressability" because they are "the part[ies] seeking to invoke federal jurisdiction." *Friends for Ferrell Pkwy LLC v. Stasko*, 282 F.3d 315, 320 (4th Cir. 2002).

Plaintiffs' asserted injuries would not be redressed by an order setting aside HHS's approval of state HCBS waiver programs. As noted above, an order invalidating the Secretary's approval of the 2010 waiver amendments cannot redress plaintiffs' alleged injuries because those amendments are no longer operative. But even when the prior 5-year HCBS waiver amendments were effective, plaintiffs' asserted injuries would not have been redressed by relief against the federal defendants because the State would have remained free under the Medicaid statute to cease providing the services that plaintiffs seek. State participation in Medicaid HCBS waiver programs is optional, and a State can terminate its participation prior to the expiration of the program's term.

* * * * *

As demonstrated above, the district court correctly dismissed plaintiffs' claims against the federal defendants. Notably, affirmance does not leave plaintiffs without an adequate remedy for their alleged injuries. To the contrary, plaintiffs have litigated

their ADA and related claims against the state defendants in this action and in the separate state court lawsuit.

CONCLUSION

For the foregoing reasons, the dismissal of the claims against the federal defendants should be affirmed.

Respectfully submitted,

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August 3, 2018

STATEMENT REGARDING ORAL ARGUMENT

The district court correctly entered judgment for the federal defendants, and the federal defendants do not believe that oral argument is necessary in this case. If this Court determines that oral argument would be helpful to its resolution of the appeal, however, the federal defendants stand ready to present argument.

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(c), I hereby certify that the foregoing brief complies with the type-volume limitation in Fed. R. App. P. 32(a)(7)(B), the typeface requirements of Fed. R. App. P. 32(a)(5), and the type style requirements of Fed. R. App. 32(a)(6). The word processing program (Microsoft Word 2010) used to prepare the brief reports that the brief is 4,757 words long. The brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 with Garamond, 14 point font.

s/ Stephanie R. Marcus
Stephanie R. Marcus

CERTIFICATE OF SERVICE

I hereby certify that on this 3rd day of August, 2018, I electronically filed the foregoing Final Brief For Federal Appellees with the Clerk of the Court for the U.S. Court of Appeals for the Fourth Circuit by using the CM/ECF system. I further certify that on this 3rd day of August, 2018, I served the foregoing Final Brief For Federal Appellees on counsel of record for plaintiff-appellant by electronic service via the CM/ECF system:

s/ Stephanie R. Marcus
Stephanie R. Marcus

ADDENDUM

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5 U.S.C. **§ 701. Application; definitions**

(a) This chapter applies, according to the provisions thereof, except to the extent that--

(1) statutes preclude judicial review; or

(2) agency action is committed to agency discretion by law.

(b) For the purpose of this chapter--

(1) "agency" means each authority of the Government of the United States, whether or not it is within or subject to review by another agency, but does not include--

(A) the Congress;

(B) the courts of the United States;

(C) the governments of the territories or possessions of the United States;

(D) the government of the District of Columbia;

(E) agencies composed of representatives of the parties or of representatives of organizations of the parties to the disputes determined by them;

(F) courts martial and military commissions;

(G) military authority exercised in the field in time of war or in occupied territory; or

(H) functions conferred by sections 1738, 1739, 1743, and 1744 of title 12; subchapter II of chapter 471 of title 49; or sections 1884, 1891-1902, and former section 1641(b)(2), of title 50, appendix;[1] and

(2) "person", "rule", "order", "license", "sanction", "relief", and "agency action" have the meanings given them by section 551 of this title.

42 U.S.C. § 1396n. Compliance with State plan and payment provisions

. . . .

(c) Waiver respecting medical assistance requirement in State plan; scope, etc.; "habilitation services" defined; imposition of certain regulatory limits prohibited; computation of expenditures for certain disabled patients; coordinated services; substitution of participants

(1) The Secretary may by waiver provide that a State plan approved under this subchapter may include as "medical assistance" under such plan payment for part or all of the cost of home or community-based services (other than room and board) approved by the Secretary which are provided pursuant to a written plan of care to individuals with respect to whom there has been a determination that but for the provision of such services the individuals would require the level of care provided in a hospital or a nursing facility or intermediate care facility for the mentally retarded the cost of which could be reimbursed under the State plan. For purposes of this subsection, the term "room and board" shall not include an amount established under a method determined by the State to reflect the portion of costs of rent and food attributable to an unrelated personal caregiver who is residing in the same household with an individual who, but for the assistance of such caregiver, would require admission to a hospital, nursing facility, or intermediate care facility for the mentally retarded.

(2) A waiver shall not be granted under this subsection unless the State provides assurances satisfactory to the Secretary that--

(A) necessary safeguards (including adequate standards for provider participation) have been taken to protect the health and welfare of individuals provided services under the waiver and to assure financial accountability for funds expended with respect to such services;

(B) the State will provide, with respect to individuals who--

(i) are entitled to medical assistance for inpatient hospital services, nursing facility services, or services in an intermediate care facility for the mentally retarded under the State plan,

(ii) may require such services, and

(iii) may be eligible for such home or community-based care under such waiver,

for an evaluation of the need for inpatient hospital services, nursing facility services, or services in an intermediate care facility for the mentally retarded;

(C) such individuals who are determined to be likely to require the level of care provided in a hospital, nursing facility, or intermediate care facility for the

mentally retarded are informed of the feasible alternatives, if available under the waiver, at the choice of such individuals, to the provision of inpatient hospital services, nursing facility services, or services in an intermediate care facility for the mentally retarded;

(D) under such waiver the average per capita expenditure estimated by the State in any fiscal year for medical assistance provided with respect to such individuals does not exceed 100 percent of the average per capita expenditure that the State reasonably estimates would have been made in that fiscal year for expenditures under the State plan for such individuals if the waiver had not been granted; and

(E) the State will provide to the Secretary annually, consistent with a data collection plan designed by the Secretary, information on the impact of the waiver granted under this subsection on the type and amount of medical assistance provided under the State plan and on the health and welfare of recipients.

(3) A waiver granted under this subsection may include a waiver of the requirements of section 1396a(a)(1) of this title (relating to statewideness), section 1396a(a)(10)(B) of this title (relating to comparability), and section 1396a(a)(10)(C)(i)(III) of this title (relating to income and resource rules applicable in the community). A waiver under this subsection (other than a waiver described in subsection (h)(2)) shall be for an initial term of three years and, upon the request of a State, shall be extended for additional five-year periods unless the Secretary determines that for the previous waiver period the assurances provided under paragraph (2) have not been met. A waiver may provide, with respect to post-eligibility treatment of income of all individuals receiving services under that waiver, that the maximum amount of the individual's income which may be disregarded for any month for the maintenance needs of the individual may be an amount greater than the maximum allowed for that purpose under regulations in effect on July 1, 1985.

(4) A waiver granted under this subsection may, consistent with paragraph (2)--

(A) limit the individuals provided benefits under such waiver to individuals with respect to whom the State has determined that there is a reasonable expectation that the amount of medical assistance provided with respect to the individual under such waiver will not exceed the amount of such medical assistance provided for such individual if the waiver did not apply, and

(B) provide medical assistance to individuals (to the extent consistent with written plans of care, which are subject to the approval of the State) for case

management services, homemaker/home health aide services and personal care services, adult day health services, habilitation services, respite care, and such other services requested by the State as the Secretary may approve and for day treatment or other partial hospitalization services, psychosocial rehabilitation services, and clinic services (whether or not furnished in a facility) for individuals with chronic mental illness.

Except as provided under paragraph (2)(D), the Secretary may not restrict the number of hours or days of respite care in any period which a State may provide under a waiver under this subsection.

(5) For purposes of paragraph (4)(B), the term "habilitation services"--

(A) means services designed to assist individuals in acquiring, retaining, and improving the self-help, socialization, and adaptive skills necessary to reside successfully in home and community based settings; and

(B) includes (except as provided in subparagraph (C)) prevocational, educational, and supported employment services; but

(C) does not include--

(i) special education and related services (as such terms are defined in section 1401 of Title 20), which otherwise are available to the individual through a local educational agency; and

(ii) vocational rehabilitation services which otherwise are available to the individual through a program funded under section 730 of Title 29.

(6) The Secretary may not require, as a condition of approval of a waiver under this section under paragraph (2)(D), that the actual total expenditures for home and community-based services under the waiver (and a claim for Federal financial participation in expenditures for the services) cannot exceed the approved estimates for these services. The Secretary may not deny Federal financial payment with respect to services under such a waiver on the ground that, in order to comply with paragraph (2)(D), a State has failed to comply with such a requirement.

(7)(A) In making estimates under paragraph (2)(D) in the case of a waiver that applies only to individuals with a particular illness or condition who are inpatients in, or who would require the level of care provided in, hospitals, nursing facilities, or

intermediate care facilities for the mentally retarded, the State may determine the average per capita expenditure that would have been made in a fiscal year for those individuals under the State plan separately from the expenditures for other individuals who are inpatients in, or who would require the level of care provided in, those respective facilities.

(B) In making estimates under paragraph (2)(D) in the case of a waiver that applies only to individuals with developmental disabilities who are inpatients in a nursing facility and whom the State has determined, on the basis of an evaluation under paragraph (2)(B), to need the level of services provided by an intermediate care facility for the mentally retarded, the State may determine the average per capita expenditures that would have been made in a fiscal year for those individuals under the State plan on the basis of the average per capita expenditures under the State plan for services to individuals who are inpatients in an intermediate care facility for the mentally retarded, without regard to the availability of beds for such inpatients.

(C) In making estimates under paragraph (2)(D) in the case of a waiver to the extent that it applies to individuals with mental retardation or a related condition who are resident in an intermediate care facility for the mentally retarded the participation of which under the State plan is terminated, the State may determine the average per capita expenditures that would have been made in a fiscal year for those individuals without regard to any such termination.

(8) The State agency administering the plan under this subchapter may, whenever appropriate, enter into cooperative arrangements with the State agency responsible for administering the program for children with special health care needs under subchapter V of this chapter in order to assure improved access to coordinated services to meet the needs of such children.

(9) In the case of any waiver under this subsection which contains a limit on the number of individuals who shall receive home or community-based services, the State may substitute additional individuals to receive such services to replace any individuals who die or become ineligible for services under the State plan.

(10) The Secretary shall not limit to fewer than 200 the number of individuals in the State who may receive home and community-based services under a waiver under this subsection.

. . . .

42 U.S.C. § 1396n. Compliance with State plan and payment provisions

. . . .

(f) Monitor of implementation of waivers; termination of waiver for noncompliance; time limitation for action on requests for plan approval, amendments, or waivers

(1) The Secretary shall monitor the implementation of waivers granted under this section to assure that the requirements for such waiver are being met and shall, after notice and opportunity for a hearing, terminate any such waiver where he finds noncompliance has occurred.

(2) A request to the Secretary from a State for approval of a proposed State plan or plan amendment or a waiver of a requirement of this subchapter submitted by the State pursuant to a provision of this subchapter shall be deemed granted unless the Secretary, within 90 days after the date of its submission to the Secretary, either denies such request in writing or informs the State agency in writing with respect to any additional information which is needed in order to make a final determination with respect to the request. After the date the Secretary receives such additional information, the request shall be deemed granted unless the Secretary, within 90 days of such date, denies such request.

42 C.F.R. § 441.307 Notification of a waiver termination.

(a) If a State chooses to terminate its waiver before the initial 3–year period or 5–year renewal period expires, it must notify CMS in writing 30 days before terminating services to beneficiaries.

(b) If CMS or the State terminates the waiver, the State must notify beneficiaries of services under the waiver in accordance with § 431.210 of this subchapter and notify them 30 days before terminating services.

§ 355.16 How do I determine the quantity of extremely hazardous substances present for certain forms of solids?

* * * * *

(b) *Solids in solution.* Multiply the weight percent of non-reactive solids in solution in a particular container by the total weight of solution in the container. Then multiply by 0.2.

* * * * *

3. Section 355.61 is amended by adding in alphabetical order the definition of "Solution" to read as follows:

§ 355.61 How are key words in this part defined?

* * * * *

Solution means any aqueous or organic solutions, slurries, viscous solutions, suspensions, emulsions, or pastes.

* * * * *

[FR Doc. 2011–9096 Filed 4–14–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 441

[CMS–2296–P]

RIN 0938–AP61

Medicaid Program; Home and Community-Based Services (HCBS) Waivers

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the regulations implementing Medicaid home and community-based services (HCBS) waivers under section 1915(c) of the Social Security Act by providing States the option to combine the existing three waiver targeting groups as identified in § 441.301. In addition, we are proposing other changes to the HCBS waiver provisions to convey expectations regarding person-centered plans of care, to provide characteristics of settings that are not home and community-based, to clarify the timing of amendments and public input requirements when States propose modifications to HCBS waiver programs and service rates, and to describe the additional strategies available to CMS to ensure State compliance with the statutory provisions of section 1915(c) of the Act.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 14, 2011.

ADDRESSES: In commenting, please refer to file code CMS–2296–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2296–P, P.O. Box 8016, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2296–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT: Kathryn Poisal, (410) 786–5940.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

Section 1915(c) of the Social Security Act (the Act) authorizes the Secretary of Health and Human Services to waive certain Medicaid statutory requirements so that a State may offer Home and Community-Based Services (HCBS) to State-specified group(s) of Medicaid beneficiaries who otherwise would require services at an institutional level of care. This provision was added to the Act by the Omnibus Budget and Reconciliation Act of 1981 (Pub. L. 97–35, enacted August 13, 1981) (OBRA'81) (with a number of subsequent amendments). Regulations were published to effectuate this statutory provision, with final regulations issued on July 25, 1994 (59 FR 37719). In the June 22, 2009 **Federal Register** (74 FR 29453), we published the Medicaid Program; Home and Community-Based Services (HCBS) advance notice of proposed rulemaking (ANPRM) that proposed to initiate rulemaking on a number of areas within the section 1915(c) program. We received 313 comments (which can be accessed at *http://www.regulations.gov/*) and held teleconferences with stakeholders. The correspondence included comments from States, health care and community support providers and associations, consumer groups, and social workers, and others. In the following sections, we discuss comments relating to questions

community; must not be located in a building that is also a publicly or privately operated facility that provides institutional treatment or custodial care; must not be located in a building on the grounds of, or immediately adjacent to, a public institution; or, must not be a housing complex designed expressly around an individual's diagnosis or disability, as determined by the Secretary. In addition, we propose that the settings must not have qualities of an institution, as determined by the Secretary. Such qualities may include regimented meal and sleep times, limitations on visitors, lack of privacy and other attributes that limit individual's ability to engage freely in the community. We invite comments on this portion of the regulations.

Through the ANPRM, we received comments suggesting that we carefully consider any adverse impact that a rule change may have on American Indians and Alaska Natives who reside on Tribal lands where living settings may differ according to cultural norms. To that end, we were advised to be careful that the language of a regulation does not unintentionally prohibit normative cultural living practices. We note that this proposed rule change does not exclude from home and community-based settings culturally appropriate settings on Tribal lands when the individual is an Indian or resides on Tribal lands where culturally acceptable group living arrangements are an integral aspect of the Tribal community. Specifically, Indian means any individual defined at 25 U.S.C. 1601(c), 1603(f), or 1679(b), or who has been determined eligible as an Indian, under 42 CFR 136.12. This means the individual:

(1) Is a member of a Federally-recognized Indian Tribe;

(2) Resides in an urban center and meets one or more of the four criteria:

(a) Is a member of a Tribe, band, or other organized group of Indians, including those Tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member;

(b) Is an Eskimo or Aleut or other Alaska Native;

(c) Is considered by the Secretary of the Interior to be an Indian for any purpose; or

(d) Is determined to be an Indian under regulations promulgated by the Secretary.

(3) Is considered by the Secretary of the Interior to be an Indian for any purpose; or

(4) Is considered by the Secretary of Health and Human Services to be an Indian for purposes of eligibility for Indian health care services, including as a California Indian, Eskimo, Aleut, or other Alaska Native.

The comments noted that persons who are older with and without disabilities may choose to live together in assisted living facilities and urged CMS to allow them to exercise this preference and receive waiver services. Similarly, some persons who are older may desire to live in retirement communities, such as continuing care retirement communities. As a result, in accordance with a person-centered plan, we will allow such settings to be permissible under the section 1915(c) HCBS program for older persons under certain circumstances, which are noted below.

However, as previously noted, the Medicaid program's rules do not define or limit other obligations States may have under the ADA and section 504 of the Rehabilitation Act for individuals who seek more integrated settings than assisted living settings (ALS) or other settings not covered by this regulation.

For the purposes of this regulation, we note that ALS for persons who are older, without regard to disability, would not be excluded from home and community-based settings when the following conditions are met:

- Individual has a lease.
- Setting is an apartment with individual living, sleeping, bathing and cooking areas, and individuals can choose whether to share a living arrangement and with whom.
- Individuals have lockable access to and egress from their own apartments.
- Individuals are free to receive visitors and leave the setting at times and for durations of their own choosing.
- Aging in place, or allowing individuals to remain where they live as they age and/or support needs change, must be a common practice of the ALS.
- Leases may not reserve the right to assign apartments or change apartment assignments.
- Access to the greater community is easily facilitated based on the individual's needs and preferences.
- An individual's compliance with their person-centered plan (in the event that the individual has shared his/her plan or the landlord is also the provider of services) is not in and of itself a condition of the lease.

We are particularly interested in gaining comments on these aspects of the proposed rule. In addition, we note that this proposal in no way preempts broad Medicaid requirements, such as an individual's right to obtain services from any willing and qualified provider of a service.

Recognizing the imperative to provide clear guidance to States and in consideration of recent proposals that have clearly exceeded reasonable standards for HCBS, we are proposing to clarify now that certain settings are not home and community-based because they are not integrated in the community. A setting that is integrated in the community is a setting that enables individuals with disabilities to interact with individuals without disabilities to the fullest extent possible. Further, we believe that such settings do not preclude individuals' ability to access community activities at times, frequencies and with persons of their choosing. Such settings are not segregated based on disability, either physically or because of setting characteristics, from the larger community. In addition, such settings will afford individuals choice in their daily life activities, such as eating, bathing, sleeping, visiting and other typical daily activities. We will continue our dialogue with a wide variety of stakeholders on other issues related to the characteristics of HCBS settings.

3. Person-Centered Planning

Underpinning all aspects of successful HCBS is the importance of a complete and inclusive person-centered planning process that addresses health and long-term services and support needs in a manner that reflects individual preferences. To fully meet individual needs and ensure meaningful access to their surrounding community, systems that deliver HCBS must be based upon a strong foundation of person-centered planning and approaches to service delivery. Through the ANPRM process, we received favorable comments regarding our interest in ensuring a person-centered approach to services and support plan development, with recommendations that we articulate expectations for such an approach.

The person-centered approach is a process, directed by the individual with long-term support needs, and may also include a representative whom the individual has freely chosen. The person-centered plan shall identify the strengths, preferences, needs (clinical and support), and desired outcomes of the individual. The person-centered process enables the individual to choose others to serve as important contributors and members of the team in the planning process.

These participants in the person-centered planning process enable and

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 430, 431, 435, 436, 440, 441 and 447

[CMS–2249–F; CMS–2296–F]

RIN 0938–AO53; 0938–AP61

Medicaid Program; State Plan Home and Community-Based Services, 5-Year Period for Waivers, Provider Payment Reassignment, and Home and Community-Based Setting Requirements for Community First Choice and Home and Community-Based Services (HCBS) Waivers

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule amends the Medicaid regulations to define and describe state plan section 1915(i) home and community-based services (HCBS) under the Social Security Act (the Act) amended by the Affordable Care Act. This rule offers states new flexibilities in providing necessary and appropriate services to elderly and disabled populations. This rule describes Medicaid coverage of the optional state plan benefit to furnish home and community based-services and draw federal matching funds.

This rule also provides for a 5-year duration for certain demonstration projects or waivers at the discretion of the Secretary, when they provide medical assistance for individuals dually eligible for Medicaid and Medicare benefits, includes payment reassignment provisions because state Medicaid programs often operate as the primary or only payer for the class of practitioners that includes HCBS providers, and amends Medicaid regulations to provide home and community-based setting requirements related to the Affordable Care Act for Community First Choice State plan option. This final rule also makes several important changes to the regulations implementing Medicaid 1915(c) HCBS waivers.

DATES: *Effective Date:* These regulations are effective on March 17, 2014.

FOR FURTHER INFORMATION CONTACT: Kathy Poisal, (410)786–5940.

SUPPLEMENTARY INFORMATION:

Table of Contents

Acronyms

Because of the many terms to which we refer by acronym in this final rule, we are listing the acronyms used and their corresponding terms in alphabetical order below.

ADA Americans with Disabilities Act of 1990 (Pub. L. 110–325)
ADLs Activities of daily living
AHRQ Agency for Healthcare Research and Quality
ANPRM Advance Notice of Proposed Rulemaking
CFC Community First Choice (1915(k) State plan Option)
CHIPRA Children's Health Insurance Program Reauthorization of 2009 (Pub. L. 111–3)
CMS Centers for Medicare & Medicaid Services
DRA Deficit Reduction Act of 2005 (Pub. L. 109–171)
EPSDT Early and Periodic Screening, Diagnosis and Treatment
FBR Federal benefit rate
FFP Federal financial participation
FPL Federal poverty line
FY Federal fiscal year
HCB Home and community based
HCBS Home and Community-Based Services
HHS Department of Health and Human Services
IADLs Instrumental activities of daily living
ICF/IID Intermediate care facility for individuals with intellectual disabilities
LOC Level of care
NF Nursing facility
OBRA'81 Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97–35)
OT Occupational therapy
PT Physical therapy
RFA Regulatory Flexibility Act
SPA State Plan Amendments
SSI Supplemental Security Income
SSI/FBR Supplemental Security Income Federal Benefit Rate
UPL Upper payment limit

I. Executive Summary

A. Purpose

This final rule amends Medicaid regulations consistent with the requirements of section 2601 of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), which added section 1915(h)(2) to the Act to provide authority for a 5-year duration for certain demonstration projects or waivers under sections 1115, 1915(b), (c), or (d) of the Act, at the discretion of the Secretary, when they provide medical assistance to individuals who are dually eligible for both Medicaid and Medicare benefits.

This final rule also provides additional limited exception to the general requirement that payment for services under a state plan must be made directly to the individual practitioner providing a service when the Medicaid program is the primary source of reimbursement for a class of individual practitioners. This exception will allow payments to be made to other parties to benefit the providers by ensuring workforce stability, health and welfare, and trainings, and provide added flexibility to the state. We are including the payment reassignment provision, because states' Medicaid programs often operate as the primary or only payer for the class of practitioners that includes HCBS providers.

In addition, this final rule also amends Medicaid regulations to provide home and community-based setting requirements related to section 2401 of the Affordable Care Act for section

term "benefit" rather than "program" to describe section 1915(i) of the Act to avoid possible confusion with section 1915(c) HCBS waiver programs. The State plan HCBS benefit shares many features with section 1915(c) waiver programs, but it is a state plan benefit, although one with very unique features not common to traditional state plan services.

Under section 1915(i) of the Act, states can provide HCBS to individuals who require less than institutional level of care (LOC) and who would, therefore, not be eligible for HCBS under section 1915(c) waivers, in addition to serving individuals who have needs that would meet entry requirements for an institution. As with other state plan services, the benefits must be provided statewide, and states must not limit the number of eligible people served.

Section 1915(i) of the Act explicitly provides that State plan HCBS may be provided without determining that, but for the provision of these services, individuals would require the LOC provided in a hospital, a nursing facility (NF), or an intermediate care facility for individuals with intellectual disabilities [2] (ICF/IID) as is required in section 1915(c) HCBS waivers. While HCBS provided through section 1915(c) waivers must be "cost-neutral", as compared to institutional services, no cost neutrality requirement applies to the section 1915(i) State plan HCBS benefit. States are not required to produce comparative cost estimates of institutional care and the State plan HCBS benefit. This significant distinction allows states to offer HCBS to individuals whose needs are substantial, but not severe enough to qualify them for institutional or waiver services, and to individuals for whom there is not an offset for cost savings in NFs, ICFs/MR, or hospitals.

To be eligible for the State plan HCBS benefit, an individual must be included in an eligibility group that is contained in the state plan, including if the state elects, the new eligibility group defined at section 1902(a)(10)(A)(ii)(XXII) of the Act. Each individual must meet all financial and non-financial criteria set forth in the plan for the applicable eligibility group.

HCBS benefits that are not otherwise available through section 1905(a) of the Act state plan services under the Medicaid Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit may be furnished to Medicaid eligible children who meet the State plan HCBS needs-based eligibility criteria, and who meet the state's medical necessity criteria for the receipt of services. In addition to meeting EPSDT requirements through the provision of 1905(a) services, a state may also meet, in part, a particular child's needs under EPSDT through services that are also available through the 1915(i) benefit. However, all Medicaid-eligible children must have full access to services required under EPSDT, and the provision of 1915(i) State plan HCBS should in no way hinder their access to such services.

Section 1915(i)(1)(H)(i) of the Act requires the state to ensure that the State plan HCBS benefit meets federal and state guidelines for quality assurance, which we interpret as assurances of quality improvement. Consistent with current trends in health care, the language of quality assurance has evolved to mean quality improvement, a systems approach designed to continuously improve services and support and prevent or minimize problems prior to occurrences. Guidelines for quality improvement have been made available through CMS policies governing section 1915(c) HCBS waivers available at *www.hcbswaivers.net* and published manuscripts available at *www.nationalqualityenterprise.com.*

Section 1915(i) provides states the option to provide home and community-based services, but does not define "home and community-based." Along with our overarching goal to improve Medicaid HCBS, we seek to ensure that Medicaid is supporting needed strategies for states in their efforts to meet their obligations under the ADA and the Supreme Court decision in *Olmstead* v. *L.C.,* 527 U.S. 581 (1999). In the *Olmstead* decision, the Court affirmed a state's obligations to provide covered program services to eligible individuals with disabilities in the most integrated setting appropriate to their needs. A state's obligations under the ADA and section 504 of the Rehabilitation Act are not defined by, or limited to, the services provided under the State's Medicaid program. However, the Medicaid program can support compliance with the ADA, section 504 of the Rehabilitation Act, and *Olmstead* through the provision of Medicaid services to Medicaid-eligible individuals in integrated settings.

We noted in the May 3, 2012 proposed rule published in the **Federal Register** (77 FR 26362), that home and community-based settings do not include nursing facilities, institutions for mental diseases, intermediate care facilities for the mentally retarded, hospitals, or any other locations that have the qualities of an institutional setting as determined by the Secretary.

While HCBS are not available while an individual resides in an institution, HCBS may be available to assist individuals to transition from an institution to the community. Recognizing that individuals leaving institutions require assistance to establish themselves in the community, we would allow states to include in a section 1915(i) benefit, as an "other" service, certain transition services to be offered to individuals to assist them in their transition to the community. We proposed that community transition services could be commenced prior to discharge and could be used to assist individuals during the period of transition from an institutional residence. Additionally, services could be provided to assist individuals transitioning to independent living in the community, as described in a letter to the State Medicaid Directors on May 9, 2002 (SMDL #02–008). We further recognize that, for short hospital stays, an individual may benefit from ongoing support through the State plan HCBS benefit to meet needs not met through the provision of hospital services that are identified in the individual's person-centered service plan, to ensure smooth transitions between acute care settings and home and community-based settings, and to preserve the individual's functions. Importantly, these services must be exclusively for the benefit of the individual, not the hospital, and must not substitute for services that the hospital is obligated to provide through its conditions of participation or under federal or state laws. However, payments for room and board are expressly prohibited by section 1915(i)(1) of the Act, except for respite care furnished in a setting approved by the state that is not the individual's residence.

Section 2601 of the Affordable Care Act adds a new paragraph to section 1915(h) of the Act to permit the Secretary, at her discretion, to approve a waiver that provides medical assistance for individuals dually eligible for Medicare and Medicaid ("dual eligibles") for an initial period of up to 5 years and renewed for up to 5 years, at the state's request. The statute defines a dual eligible as: "an individual who is entitled to, or enrolled for, benefits under part A of title XVIII, or enrolled for benefits under part B of title XVIII, and is eligible for medical assistance

[2] While the Social Security Act still refers to these types of facilities as intermediate care facilities for the mentally retarded (ICFs/MR), the language used in this rule reflects "intellectual disability" as the appropriate way to discuss this type of disability, based on Rosa's Law and we now refer to this types of facility as an intermediate care facility for individuals with intellectual disabilities (ICF/IID).

and who will receive section 1915(i) of the Act services, or individuals with income up to 300 percent of the SSI/FBR, who would be eligible under an existing section 1915(c), (d) or (e)[4] waiver or section 1115 waiver approved for the state and who will receive section 1915(i) services. These individuals do not have to be receiving services under an existing section 1915(c), (d) or (e) waiver or section 1115 waiver; the individual just has to be determined eligible for the waiver.

Comment: One commenter indicated that there is not a lot of difference between 300 percent FBR and 150 percent FPL. In 2012 the amounts were $2094 versus approximately $1400 per month. The commenter believes that having two income levels to administer will cause more work for the states and make explaining the program more confusing. The commenter recommended that for all 1915(i) services, the income standard be 300 percent of the SSI/FBR.

Response: The statute does not permit the income standard to be raised to 300 percent of the SSI/FBR for all individuals receiving 1915(i) services. Electing the new eligibility group specified at § 435.219 and § 436.219 in order to provide state plan HCBS to individuals who were not previously eligible to receive these services is strictly a state option. Therefore, if a state believes that the requirements for this eligibility group are too burdensome, the state does not have to elect to cover this optional eligibility group.

Comment: One commenter believes that existing financial eligibility rules should remain in place.

Response: Electing any changes to financial eligibility set forth in this final rule are strictly a state option.

5. State Plan Home and Community-Based Services Under Section 1915(i)(1) of the Act (§ 441.710) (Proposed § 441.656) and Community First Choice State Plan Option: Home and Community-Based Setting Requirements (§ 441.530)

a. Home and Community-Based Settings Under 1915(i) and 1915(k) of the Act

To implement the statutory requirement that the benefit be "home and community-based," we proposed to require in § 441.656(a) that the individual reside in the home or community, not in an institution, and that the settings must have qualities of community-based settings prescribed by the Secretary. We stated our recognition of the need for a consistent definition of this term across Medicaid HCBS, and our goal to align the final language pertaining to this topic across the regulations for sections 1915(i), 1915(k), and 1915(c) of the Act Medicaid HCBS authorities.

Section 1915(i) of the Act provides states the option to provide home and community-based services, but does not define "home and community-based." Along with our overarching interest in making improvements to Medicaid HCBS, we seek to ensure that Medicaid is supporting needed strategies for States in their efforts to meet their obligations under the ADA and the Supreme Court decision in *Olmstead* v. *L.C.,* 527 U.S. 581 (1999). We proposed language defining the qualities and requirements for settings in which section 1915(i) of the Act services and supports could be provided and sought additional comments on this issue. Instead of attempting to provide one singular definition to encompass all settings that are home and community-based, we described the qualities that apply in determining whether a setting is community-based. We stated that we would expect states electing to provide HCBS under section 1915(i) of the Act to include a definition of home and community-based settings that incorporates these qualities, and that we would review all SPAs to determine whether they propose settings that are home and community-based.

In the proposed rule, we stated that we would permit states with approved section 1915(i) of the Act SPAs a reasonable transition period, a minimum of one year, to come into compliance with the HCBS setting requirements that are promulgated in our final rule.

Overall, we received 280 comments in response to the HCB settings section of the proposed rule regarding 1915(i) State plan HCBS and 1915(k) CFC. Commenters included advocacy organizations, individuals receiving services, family members, friends and guardians of individuals receiving services as well as providers, government entities and the general public. Because we are proposing the same requirements for home and community-based settings in regulations implementing 1915(i) and 1915(k), we are discussing comments pertaining to both in this section. The comments were mixed, with commenters providing both support and disagreement within subsections of the HCBS settings provision. A few of the issues that elicited a substantial number of comments are: qualities, integration, providers, choice, accessibility and privacy in addition to general comments.

Comment: We received many comments related to this section of the proposed rule. These comments are reflected as follows:

Many commenters expressed concern about the effect the criteria will have on existing home and community-based services, and expressed concern that the proposed rule will eliminate community based-services that elderly individuals and people with disabilities are currently receiving. Several commenters suggested eliminating all provisions that restrict the consumer's freedom of choice regarding the residential settings in which they can utilize their Medicaid funds, stating that the qualities and characteristics of home are determined by the individual.

Some commenters stated that affordable rental options, especially those in apartment complexes where home maintenance responsibilities are handled by the landlord, are hard to find or non-existent in some communities. They indicated that lack of affordable housing is a huge challenge for people seeking to live in the community while being supported for severe disabilities, and that many individuals who experience multiple disabilities need housing that is tailored for their specific physical needs. These commenters stressed that group homes that were built and owned by a third party, specifically for the purpose of serving people with disabilities, would not be available if they tried to rent on the open market and that ruling out such homes for HCBS funding imposes further hardship and segregation on the population in need of HCBS.

One commenter believes the requirements will drive up costs.

Some commenters believe that the changes would effectively eliminate their freedom to provide their adult child a setting that is protected from exposure to community members that do not understand the effect of a community's environment on individuals with disabilities.

One commenter indicated that if adopted, the criteria would have a significant adverse impact on its ability to continue to serve individuals with the most significant disabilities in the community. The language included in the proposed regulation would: (1) Thwart informed choice by negating or severely restricting longstanding program options and opportunities to provide services and supports expressly authorized by the HCBS provisions of

[4] 1915(d) and (e) waivers are State options to provide HCBS to the elderly and to individuals with disabilities, respectively. Currently, no State elects to provide services under either of these authorities.

their policy and procedures if they do not already exist.

Comment: One commenter recommended the following changes to the proposed language: "The unit or room is a specific physical place that, if a 'family care home', includes a private bedroom, and if not a 'family care home', includes, at a minimum, its own kitchen facilities, sleeping area, and private bathroom with toilet, sink and shower or bathtub, that can be owned, rented or occupied . . ."

Response: We appreciate the commenter's suggestions, however, we will not revise the rule to include these types of specifications as they would be overly prescriptive.

Comment: One commenter requested that we revise the regulation to specify that the unit can be owned, rented or occupied under another legally enforceable agreement by the individual receiving services "or his/her chosen surrogate, who must not be an agent of the service provider," could be inserted.

Response: We do not believe the commenter's recommendation to add language regarding a surrogate is necessary. The HCBS regulations already address this in the definition of individual's representative.

Comment: Several commenters supported giving individuals who receive HCBS in provider-owned or operated residential settings protections under landlord tenant law, and suggested adding protections afforded by the ADA to this section to ensure that individuals living in these settings whose health needs change are afforded appropriate accommodations (such as increased staff), in order to continue living in the setting.

Response: While we do not administer or enforce the ADA, we note that Medicaid regulations prohibit discrimination in State Medicaid programs (§ 430.2, § 435.901, § 435.905, and § 435.908). As these regulations apply in determining eligibility and administering the Medicaid program generally, it is not necessary to amend this regulation on this subject.

Comment: A few commenters recommended the word "unit" be replaced with "room" throughout the document.

Response: We do not agree with the recommendation to remove the term unit, but to provide additional clarification, we have revised the language to add the term "dwelling" since this is the common term used under prevailing state and local landlord/tenant laws.

Comment: Several commenters agreed with the list of requirements for provider owned and controlled residential settings. One commenter added that preservation of the right to privacy, including having a lockable unit and the ability to control access to the unit, and self-control of the participant's schedule, are also important indicators for basic human dignity. Another commenter noted that individuals with disabilities should be afforded the same rights as anyone else in the country.

Response: We agree and appreciate the commenter's support.

Comment: One commenter indicated that "the freedom to furnish and decorate their sleeping or living unit" could use clarification noting that there are many landlords that have restrictions on water beds, or permission prior to painting. The commenter added that all rules relating to entrance locks, roommates, furniture preferences, daily schedules, food, visitors, etc., must include caveats as to feasibility and reasonableness.

Response: These requirements pertain to settings that are owned or controlled by a provider. Landlord tenant laws may allow landlords to set reasonable limits as long as the limits are not discriminatory or otherwise deny rights granted to tenants under the state law. Therefore, we have added additional language to this requirement to clarify that, in a provider-owned or controlled setting, the individual's freedom to furnish and decorate sleeping or living units may contain limits within the scope of the lease or agreement.

Comment: One commenter expressed support of the criteria when an individual lives alone, but wanted to know in situations where an individual chooses to live with a roommate who is responsible for collaborating schedules and ensuring that one person's right to have visitors does not infringe on the privacy of the other.

Response: While this is not specifically addressed through regulation, we note that there are many ways to address this concern, including through good roommate communication.

Comment: Several commenters recommended that "their" be changed to "the," since "individual" is singular but "their" is plural.

Response: We agree with the commenter and have revised the regulation accordingly.

Comment: One commenter noted that individuals requiring care and services will have their privacy limited in some fashion while those care and services are being provided and suggested the following revision to § 441.530 and § 441.656(a)(1)(vi)(B): Each individual has privacy in their sleeping or living unit, to the extent care and services are provided in accordance with the individual's assessed needs.

Response: We do not believe the recommended revision is necessary as there is a general requirement that services are provided in accordance with an individual's assessed needs. This requirement is expressed at § 441.530(a)(1) and § 441.710(a)(1) and also under person-centered planning provision of the regulations for sections 1915(c), 1915(i) and 1915(k) of the Act.

Comment: A few commenters disagreed with the proposed language requiring that units have lockable doors. The commenters believe that this requirement poses a safety risk in the event of an emergency and added that clarification is also needed on a unit owned by the resident who may not want to provide the appropriate staff with keys to his/her door. The commenters pointed out that in some apartment buildings the entrance door is the unit's door and asked if the resident owns the unit whether he/she will be required to provide appropriate staff with keys.

Response: We disagree that the recommended change is necessary. However, the requirement for a lockable entrance door may be modified if supported by a specific assessed need and justified and agreed to in the person-centered service plan. Additionally, the state must ensure adherence to requirements set forth at § 441.530(a)(1)(vi)(F) and § 441.710(a)(1)(vi)(F).

We would like to clarify that this regulation does not require individuals to provide keys to anyone. The language is meant to curtail the issuing of resident keys to all employees or staff regardless of the employee's responsibilities, thus granting employees unlimited access to an individual's room. This provision indicates that only appropriate individuals should have access to an individual's room. For example, it may be appropriate for the property manager to have keys, but it might not be appropriate for the individual working at a reception area.

Comment: One commenter recommended the additional phrase "if necessary" be added after "appropriate staff," as there may be occasions when the particular setting will not have staff members holding keys to living units. Several commenters recommend adding the phrase "as appropriate" at the end of the provision since there may be times when a setting will not have staff members with keys to living units.

Response: We agree with the second commenter's concern and have